

BENZ RESEARCH & DEVELOPMENT

510(k) Premarket Notification

AUG - 6 2007

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K062854**

**Applicant Information:**

Date Prepared: 8/03/2007

Name: Benz Research & Development  
6447 Parkland Drive  
Sarasota, FL 34243

Contact Person: Arthur Ward  
Regulatory Consultant  
Benz Research & Development

Phone number: 941-758-8256

Fax number: 941-758-1191

**Device Information:**

Device Classification: Class II

Classification number: LPL

Classification Name: Lens, Soft Contact, Daily Wear

Trade Name: Benz-G 4X (hioxifilcon D) Lathed Sphere and  
Toric Lenses

**Purpose of the 510(k) Submission:**

Benz Research & Development is requesting clearance from the FDA to manufacture and market Benz-G 4X (hioxifilcon D) Lathed Lenses.

**BENZ RESEARCH & DEVELOPMENT**  
510(k) Premarket Notification

**Predicate Devices:**

The Benz-G 4X 54% (hioxifilcon D) lathed soft contact lens is substantially equivalent to the Extreme H<sub>2</sub>O<sup>®</sup> 54% (hioxifilcon D) molded soft contact lens already cleared under 510(k) K051430.

In addition, Benz-G 4X (hioxifilcon D) lathed lens is manufactured at Benz Research & Development according to the same manufacturing processes as the following previously cleared hydrophilic contact lenses:

Benz-G 5X (hioxifilcon A)	K952620	(MAF-700)
Benz-G 3X (hioxifilcon B)	K964528	(MAF-816)

**Device Description:**

Benz-G 4X 54% (hioxifilcon D) lathed soft contact lenses are hemispherical shells and are available as spherical or toric lens designs. The Benz-G 4X 54% (hioxifilcon D) lathed soft contact lens is fabricated from hioxifilcon D, which is a non-ionic, copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 46% hioxifilcon D and 54% water by weight when immersed in normal buffered saline solution buffered. The lens is available with a blue visibility handling tint, phthalocyanato (2) - (copper).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped. However, it will return to its proper configuration when completely rehydrated in the proper storage solution.

**Intended Use (Indications):**

The Benz-G 4X 54% (hioxifilcon D) soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for

# BENZ RESEARCH & DEVELOPMENT

## 510(k) Premarket Notification

frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

### Comparison to Predicate Device:

Side by side comparison testing was conducted on the molded lenses Extreme H<sub>2</sub>O<sup>®</sup> 54% (hioxifilcon D) cleared under 510(k) K051430 and lathed lenses manufactured by Benz Research & Development from hioxifilcon D material.

	Predicate Device	New Device
	Extreme H <sub>2</sub> O <sup>®</sup> 54% Molded Lens	Benz-G 4X Lathed Lens
Intended Use:	Intended for daily wear for the correction of visual acuity in aphakic and non aphakic persons with non-diseased eyes that are myopic or hyperopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters.  Lenses are intended for frequent and / or planned replacement wear as prescribed by the eye care practitioner.	Intended for daily wear for the correction of visual acuity in aphakic and non aphakic persons with non-diseased eyes that are myopic or hyperopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters.  Lenses are intended for frequent and / or planned replacement wear as prescribed by the eye care practitioner.
Lens Material:	Hioxifilcon D	Hioxifilcon D
Material Classification:	FDA Group 2 (> 50% H <sub>2</sub> O, non-ionic polymer)	FDA Group 2 (> 50% H <sub>2</sub> O, non-ionic polymer)
Production Method:	Cast-Molded	Lathe-Cut
Water content:	54% +/- 2	54% +/- 2
Refractive Index:	1.414 hydrated	1.408 hydrated
Light Transmission:	Greater than 95% T	Greater than 95% T
Tint	Blue Phthalocyanato (2) – (copper)	Blue Phthalocyanato (2) – (copper)
Oxygen Permeability (ANSI Z80:2004 upgraded polarographic method) in Fatt Dk units	21	18

**BENZ RESEARCH & DEVELOPMENT**  
510(k) Premarket Notification

Specific Gravity	1.300 (dry)	1.299 (dry)
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**Non-clinical Testing:**

The following toxicological testing was performed in accordance with the regulations set forth in 21 CFR, Part 58

- a) Agar Diffusion Test - ISO  
The test article is considered non-cytotoxic
- b) Systemic Injection Test – ISO  
The test article did not induce a significantly greater biological reaction than their control articles.
- c) Primary Ocular Irritation – ISO  
The test article is considered to be a non-irritant

**Clinical Data:**

It was determined that clinical studies were not necessary to establish the safety and effectiveness of the Benz-G 4X (hioxifilcon D) lathed lens. The Benz-G 4X (hioxifilcon D) lathed lens is formulated from the same components as the previously cleared Extreme H<sub>2</sub>O<sup>®</sup> 54% (hioxifilcon D) molded contact lens. The physical / chemical / toxicological results of the Benz-G 4X (hioxifilcon D) lathed lens also show that it is substantially equivalent to the Extreme H<sub>2</sub>O<sup>®</sup> 54% (hioxifilcon D) molded contact lens.

**Conclusion:**

The information provided in this premarket submission establishes that the Benz-G 4X (hioxifilcon D) lathed lens is substantially equivalent in terms of intended use, materials, toxicological and physiochemical properties to the predicate device, Extreme H<sub>2</sub>O<sup>®</sup> 54% (hioxifilcon D) molded contact lens. In addition, The Benz-G 4X (hioxifilcon D) lathed lens is manufactured at Benz Research & Development according to the same manufacturing processes as the following previously cleared hydrophilic contact lenses:

Benz-G 5X (hioxifilcon A)    K952620        (MAF-700)  
Benz-G 3X (hioxifilcon B)    K964528        (MAF-816)

The Benz-G 4X (hioxifilcon D) material is formulated from the same components as the previously cleared Benz-G 5X (hioxifilcon A) and Benz-G 3X (hioxifilcon B), but with a different ratio of components that bracket the new material between these two cleared materials.

## BENZ RESEARCH & DEVELOPMENT

### 510(k) Premarket Notification

Benz-G 4X (hioxifilcon D) lathed lens therefore meets the requirements of substantial equivalence and is as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 6 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Benz Research & Development  
c/o Arthur J. Ward, Ph.D.  
AJW Technologies Consultants, Inc.  
962 Allegro Lane  
Apollo Beach, FL 33572

Re: K062854

Trade/Device Name: Benz-G 4X (hioxifilcon D) Lathed Sphere and Toric Lenses  
Regulation Number: 21 CFR 886.5925  
Regulation Name: Lens, Soft Contact, Daily Wear  
Regulatory Class: Class II  
Product Code: LPL  
Dated: July 25, 2007  
Received: July 30, 2007

Dear Dr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

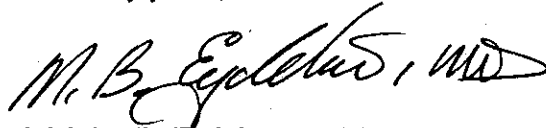
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. B. Eydelman, MD". The signature is fluid and cursive, with the "MD" at the end being more distinct.

Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

BENZ RESEARCH & DEVELOPMENT  
510(k) Premarket Notification

**INDICATIONS FOR USE STATEMENT**

Device Name: Benz G 4X (Hioxifilcon D) soft contact lens

INDICATIONS FOR USE:

The Benz G 4X (Hioxifilcon D) soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribe for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ming-chuan Shih

(Division Sign-Off)

Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K062854

MS for AS  
Prescription Use X  
(Per 21 CFR 801.109)

or

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)